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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,482

11/19/2003

Naveen Arora

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

05/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/715,482</p>	<p><b>Applicant(s)</b> ARORA ET AL.</p>	
	<p><b>Examiner</b> VANESSA L. FORD</p>	<p><b>Art Unit</b> 1645</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 17 April 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: NONE.  
Claim(s) objected to: NONE.  
Claim(s) rejected: 1, 3-8 and 36-37 under 35 U.S.C. 102(a) and 102(b), pages 2-9, paragraphs 3 and 4.  
Claim(s) withdrawn from consideration: NONE.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Vanessa L. Ford/  
Examiner, Art Unit 1645

Continuation of 5. Applicant's reply has overcome the following rejection(s): 102(b) of claims 1, 3-8, 36-38 as anticipated by Verma et al, pages 9-12, paragraph 5.

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(a) as anticipated by Bijli et al (Clin. Exp. Allergy, January 2003) is maintained for the reasons set forth on pages 2-6 paragraph 3 of the Final Office Action.

#### Applicant's Arguments

Applicant urges that Bijli et al, 2003 discloses a 67 kDa protein that is identified in an SDS-PAGE gel solely by molecular weight. Applicant urges that some claim limitations are structural, e.g. devoid of any carbohydrate moiety". Applicant urges that other claim limitations are functional, e.g. inhibits proteolytic cleavage of protective antigen of *Bacillus anthracis* in a dose dependent manner. Applicant urges that that description analysis of protein fractions by SDS electrophoresis and identification of the presence of proteins at 67 kDa molecular weight as disclosure of a purified 67 kDa inherently has the same properties as the claimed protein. Applicant urges in regards to functional recitations in the claims, these relate to maintenance of the folded, tertiary structure of the protein which is abolished by the SDS gel electrophoresis technique. Applicant urges even if the proteins of Bijli (2003) and the claimed proteins are indeed individual, purified proteins and have the same amino acid sequence as the claimed proteins, they lack the biological activities recited in the claims. Applicant urges that SDS-PAGE is known in the art to separate proteins on the basis of charge to weight ratio. Applicant urges that any band at a particular molecular weight is likely to include several different protein having distinct properties.

#### Examiner's Response to Applicant's Arguments

Applicant's arguments filed March 17, 2009 have been fully considered but they are not persuasive.

Bijli et al, 2003 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2003 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2003 makes reference to a purified 67 kDa protein from *Imperata cylindrica* in the Introduction section on page 65 of Bijli et al. It is also noteworthy to mention that the protein content of the 67 kDa protein as taught by Bijli et al, 2003 was estimated by modified Lowry's method just like the claimed protein (page 66, 1st column). It is further noted that claimed protein was analyzed by SDS-PAGE just like the protein as disclosed by Bijli et al 2003.

It should be remembered that the term "isolate" is defined as separating something from something else. The prior art teaches that the 67-kDa protein has been extracted by EACA and isolated on SDS gel. See page 68. It should be remembered that the product (e.g. 67-kDa protein) of Bijli et al, 2003 is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPO 964 (CAFC 1985); *In re Marosi*, 218 USPO 289, 29222-293 (CAFC 1983); *In re Brown*, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. There is no evidence on the record to show that the claimed 67 kDa protein isolated from *Imperata cylindrica* is any different from the claimed protein isolated from *Imperata cylindrica*.

To address Applicant's comment regarding SDS-PAGE, while it is true that SDS-PAGE separates proteins based on charge to weight ratio, it should be noted that, Bijli et al teach a 67 kDa protein from *Imperata cylindrica*. Bijli et al, 2003 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(b) as anticipated by Bijli et al (Journal of Immunological Methods 260, February 2002, p. 91-26) is maintained for the reasons set forth on pages 6-9, paragraph 4 of the Final Office Action.

#### Applicant's Arguments

Applicant urges that Bijli et al, 2002 discloses a 67 kDa protein that is identified in an SDS-PAGE gel solely by molecular weight. Applicant urges that some claim limitations are structural, e.g. devoid of any carbohydrate moiety". Applicant urges that other claim limitations are functional, e.g. inhibits proteolytic cleavage of protective antigen of *Bacillus anthracis* in a dose dependent manner. Applicant urges that description analysis of protein fractions by SDS electrophoresis and identification of the presence of proteins at 67 kDa molecular weight as disclosure of a purified 67 kDa inherently has the same properties as the claimed protein. Applicant urges in regards to functional recitations in the claims, these relate to maintenance of the folded, tertiary structure of the protein which is abolished by the SDS gel electrophoresis technique. Applicant urges even if the proteins of Bijli (2002) and the claimed proteins are indeed individual, purified proteins and have the same amino acid sequence as the claimed proteins, they lack the biological activities recited in the claims. Applicant urges that SDS-PAGE is known in the art to separate proteins on the basis of charge to weight ratio. Applicant urges that any band at a particular molecular weight is likely to include several different protein having distinct properties.

#### Examiner's Response to Applicant's Arguments

Applicant's arguments filed March 17, 2009 have been fully considered but they are not persuasive.

Bijli et al, 2002 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract). Bijli et al, 2002 teach an isolated protein because the protein is analyzed by SDS-PAGE just like the claimed protein. See page 92. It is also noteworthy to mention that the protein content of the 67 kDa protein as taught by Bijli et al, 2002 was estimated by modified Lowry's method just like the claimed protein (page 92, 1st column).

It should be remembered that the term "isolate" is defined as separating something from something else. The prior art teaches that the 67-kDa protein has been extracted by EACA and isolated on SDS gel. See page 68. It should be remembered that the product (e.g. 67-kDa protein) of Bijli et al, 2002 is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPO 964 (CAFC 1985); *In re Marosi*, 218

USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. There is no evidence on the record to show that the claimed 67 kDa protein isolated from *Imperata cylindrica* is any different from the claimed protein isolated from *Imperata cylindrica*. To address Applicant's comment regarding SDS-PAGE, while it is true that SDS-PAGE separates proteins based on charge to weight ratio, it should be noted that , Bijli et al teach a 67 kDa protein from *Imperata cylindrica*. Bijli et al, 2002 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

It should be noted, as indicated above, the rejection of claims 1, 3-8 and 36-38 under 35 U.S.C. 102(b), pages 5-12, paragraph 5 of the Final Office action has been withdrawn based on reconsideration of the Arora declaration filed 2/6/06, Verma et al, page 255 and Applicant's arguments.